

## **Policy on Product Safety**

### **Background**

The Astellas' business philosophy is to contribute toward improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. This policy documents Astellas' commitment and principles as they relate to the safety and reliability of Astellas investigational compounds and authorized medicinal products. The policy demonstrates product safety is a steadfast priority throughout the corporation.

### **Policy**

Astellas is committed to:

- compliance with all legal and regulatory requirements for pharmacovigilance activities and responsibilities
- preventing any harm arising from the use of Astellas products
- protecting patient and public health, utilizing the most current methodologies for comprehensive medical and scientific safety data analyses
- providing timely and reliable safety information to all Astellas stakeholders.

The policy further ensures use of a global pharmacovigilance system to continuously monitor the safety profile of Astellas products and to detect any changes to their risk-benefit balance. The system is supported by a robust organizational structure, human resources, information technology and functional processes focused on the safe, effective and appropriate use of our medicines. Astellas is committed to carrying out the intent of the global product safety system. Overall, patient safety is embedded within the entire organization, and this policy supports that position.